

**REMARKS**

Reconsideration is respectfully requested in view of Applicants' amendments and remarks herein.

With respect to the amendments to the claims, generic claim 1 now recites a method for treating a tumor in which the specified dose of benzyl alcohol (hereinafter "BA") is administered in combination with vitamin C. No new issues for consideration are presented since previous claims 4, 6 and 7 as submitted in the Supplemental Amendment filed April 14, 2006 recited the combination of benzyl alcohol and vitamin C, with claims 6 and 7 also including the dosage for BA. With the entry of this 1.116 Amendment, the claims under consideration would be claims 1 - 3, 16 and 17.

In the final Office Action, in Paragraphs 1) and 2) thereof, claims 1-3 were rejected as being anticipated under 35 U.S.C. § 102(b) and (a), respectively. These rejections are rendered moot in view of the amendments set forth above at this time.

In Paragraph 4 of the Office Action, claims 1-4, 6-7 and 16-17 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious to a person of ordinary skill in the art over Casciari in view of reference PP-1457, further in view of Stedman's Medical Dictionary. Casciari was cited as teaching that vitamin C has anticancer properties in breast cancer, for example. Reference PP-1457 was cited as teaching that BA induced cell death by apoptosis in stomach cancer cells.



Stedman's was cited as providing a definition for necrosis. The Examiner concluded that it would have been obvious to a person of ordinary skill in the art to combine vitamin C and BA into a composition for treating cancerous tumors because each of the two ingredients is taught by the prior art to be useful for the same purpose.

The newly submitted primary reference of Casciari is in one aspect similar to the present invention, in that it describes in one embodiment thereof the treatment of cancer using vitamin C in combination with a second ingredient, the second ingredient in Casciari's case being lipoic acid. However, a careful review of Casciari clearly shows that the present combination of BA with vitamin C is also patentable over the prior art that existed prior to Casciari and also over Casciari itself.

As set forth at col. 1, lines 9-11 of Casciari, vitamin C, according to Casciari, "has been shown to be selectively toxic toward tumor cells, but at doses that are too high to be achieved clinically". Casciari further notes at col. 1, lines 39-41, that at a dose of 10 grams per day, clinical trials with vitamin C were successful in some cases but not others, and at very high doses, vitamin C is preferentially toxic to tumor cells. Although not clearly recited, it appears that the dose of 10 grams per day mentioned by Casciari is stated as being a dose on the low side, and not the very high dose those preferentially toxic to tumorous cells. Furthermore, in the last paragraph in col. 1, Casciari discusses a plasma level of vitamin C required for effective treatment of tumors.



After discussing the background to his invention, Casciari states in col. 2, at lines 33-38 that the basis of his invention is the discovery that the concentration of vitamin C to induce cytotoxicity in a solid tumor model is significantly reduced when the vitamin C is administered in combination with lipoic acid. Thus, as set forth at col. 2, lines 46-49, according to Casciari, the importance of using lipoic acid in combination with vitamin C is that the level of vitamin C required for effective tumor toxicity is reduced to a level that has been successfully replicated in vivo.

With the above in mind, Applicants now turn to the discussion of their invention regarding the combination of BA with vitamin C to treat tumors. First of all, the Examiner has not suggested nor is there any reason on the record to equate the BA of the present invention with the lipoic acid of Casciari. Indeed, the Examiner appears to clearly recognize this distinction because of his recitation of the PP-1457 reference.

Claim 1 as amended herein recites that the BA and the vitamin C are used in a combination dose sufficient to treat the tumor. As set forth at the top of page 8 of the application as filed, the vitamin C can be used in a range of 0.1 to 10 times 1 part of BA by weight to effect the combination treatment of the present invention. The dose for the BA is up to 50 mg per tumor volume (cm<sup>3</sup>). Furthermore, in the Certified Experiment Result 2 of the 1.132 Declaration submitted April 3 and 14, 2006, various combinations of BA and vitamin C are utilized at a ratio of BA to vitamin C of 1:10. The doses are in micrograms per milliliter, with 250 micro liters



representing  $\frac{1}{4}$  of each cell sample. Obviously, these doses use an experimental assay plus the doses disclosed in the application as filed for vitamin C represent a dosage range for vitamin C that does not equate to the very high doses of vitamin C when used alone required for toxicity to tumorous cells.

Applicants respectfully submit that they have found a synergistic effect between use of BA plus vitamin C in the treatment of tumors, and this synergistic effect is clearly evident in the above noted Certified Experiment Result 2 of the 1.132 Declaration. This synergistic effect between BA and vitamin C is nowhere shown in the prior art, nor suggested by the prior art. Indeed, it can be said that the presently claimed invention is allowable analogously to the allowability of the Casciari convention.

### **CONCLUSION**

In conclusion, Applicants respectfully submit that the 35 U.S.C. § 103 rejection should be reconsidered and withdrawn. The prior art does not teach or suggest the combination of BA with vitamin C, in synergistic doses as found by Applicants, for use in the treatment of tumor cells. Therefore, reconsideration and allowance of independent claim 1 and remaining dependent claims 2, 3, 16 and 17 are believed to be proper, and such action is earnestly solicited.



AMENDMENT UNDER 37 C.F.R. §1.116  
U.S. Appln. No. 10/611,902

Attorney Docket No.: Q76104

If any points remain in issue which the Examiner feels may be resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the issue fee and the publication fee, to the Deposit Account No. 19-4880. Please also credit any overpayments to said deposit account.

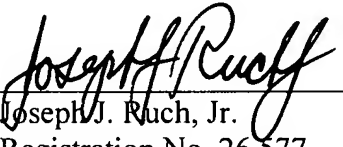
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